PRESENTATION FOR CSPA MANAGEMENT

Agenda Item: Similarity Clinic. What constitutes a Me Too? What are the mechanics of the Clinic?

Benefits of a Similarity Clinic

- More efficient process for handling substantially similar claims
- Ensures more consistent decision-making

Similarity Clinic – Basic Steps

- Action is routed to Similarity Clinic (SC) following 21 day screen by front end process.
- RD actions to RD and AD actions to AD.
- RD, AD, PRD and BPPD meet twice a week to examine new actions.
- If similar and no product chemistry then action is assigned to a reviewer.

Data package

- The proposed product should have a label, toxicity profile (if available) of the cited product and the Confidential Statement of Formulation (CSF) for the proposed product.
- The reviewer requests the last volume of the jacket for the cited product. This volume contains the CSF for the cited product.

Timelines and other Considerations

- After 21 day screen the action is routed to the Similarity Clinic.
- The Clinic's review goal is 30 days.
- A Product Chemist is part of the Clinic. Efficacy reviewers will attend on an as needed basis.
- Even after a completeness check, a detailed review of the product chemistry may identify a problem.
- The Similarity Clinic serves as the vehicle for the preliminary technical screen.

Action: No Product Chemistry – Determined to Be Substantially Similar

- If no product chemistry data are submitted the cited CSF and proposed CSF must be identical (100% repack).
- SC Reviewer will locate review of the acute toxicity six pack for the cited product in databases.
- The similarity review memorandum is written and stored in IHAD (Integrated Hazard Assessment Database). The completed action and regulatory jacket is then routed to the PM.

Action: Product Chemistry Submitted Determined to Be Substantially Similar

- If product chemistry data are submitted, the reviewer completes the toxicity review and makes the similarity determination pending PC review. The action is then routed to PM. The PM then sends the action with product chemistry for review. Product chemistry review has a longer time line under PRIA (depending on the action code).

Action – determined Not to Be Substantially Similar

- If either or both acute tox or pc fails then package is rejected.
- If the action is determined not to be substantially similar, the Similarity Clinic Executive Secretary contacts the applicant. The applicant has 10 business days to address the problem, likely by citing another product.
- Applicant is given 2 opportunities to correct problem. If not corrected on 2nd try, the Executive Secretary writes a rejection letter for signature by the Deputy Office Director (DOD).
- The OPP deficiency letter needs to go out within the preliminary technical screen time frame (45 days).

Results: October 2012 to Present

- RD: 74 similarity determinations processed There has been one rejection.
- AD: 35 similarity determinations processed. There has been one rejection.

Issues

- For a cite-all action, the applicant must still identify a specific product.
- If product chemistry for the cited and proposed products is not identical, then the proposed product must submit new product chemistry data.

PRIA 3 (RD)

- RD: Actions involving cited acute toxicity data are R300, R301 and R310. These actions must submit product specific chemistry data Groups (A & B).
- Actions that cite acute toxicity data but claim to be identical or 100% repack are R331. These actions do not need to submit product chemistry.

PRIA 3 (AD)

- AD: Actions involving cited acute toxicity data are A530, A531, A532, A540 and A570. These actions must submit product specific chemistry data Groups (A & B).
- All types of actions except for new a.i.s and new uses may be reviewed by SC if bridging data.
- Actions that cite acute toxicity data but claim to be identical or 100% repack are A530. These actions do not need to submit product chemistry.

Questions

Executive Secretary:
Marianne Lewis
Lewis.Marianne@epa.gov
(703) 308-8043

John Redden Acting Chief
Technical Review Branch
Redden.john@epa.gov
(703) 305-1969